

Express Mail No.: EM 553 193 519 US

PATENT APPLICATION

of

Arthur C. Coffey

for

COMBINATION SIS AND VACUUM BANDAGE AND METHOD

Attorney Docket 7175-67882

INDS02 CYS 369183v1

COMBINATION SIS AND VACUUM BANDAGE AND METHOD

This application claims priority under 35 U.S.C. 119(e) to U.S. Provisional Application Serial No. 60/206,226, filed May 22, 2000, which is expressly 5 incorporated by reference herein.

Background of the Invention

The present invention relates to wound care and more particularly to the provision of an SIS wound care cover used in combination with a vacuum 10 bandage. The invention contemplates both apparatus and a method for using the apparatus.

It is known to use small intestine submucosa (SIS) in wound care treatment, particularly the application of layers of SIS directly upon an open wound that has been debrided and cleaned. SIS is described in the following U.S. Patents: 15 5,855,619, 5,866,414, 5,753,267, 5,762,966, 5,755,791, 4,902,508, 4,956,178, 5,275,826, 5,281,422, 4,352,463, 5,372,821, 5,445,833, 5,516,533, 5,573,784, 5,645,860, 5,641,518, 5,711,969, and 5,695,998. These patents are hereby incorporated herein by reference for purposes of disclosing the nature of SIS.

SIS has been described as a natural acellular biomaterial used to repair, 20 support, and stabilize a wide variety of anatomical defects and traumatic injuries. See, for example, Cook® Online New Release provided by Cook Biotech at “www.cookgroup.com”. The SIS material is a tissue engineered collagen matrix derived from porcine small intestinal submucosa that models the qualities of its host when implanted in human soft tissues. Further, it is taught that the SIS material 25 provides a natural scaffold-like matrix with a three-dimensional structure and biochemical composition that attracts host cells and supports tissue remodeling. Surgisis™ Soft Tissue Repair Biomaterial and Oasis™ Wound Dressing Biomaterial are available for remodeling partial thickness skin injuries (Cook Biotech, Bloomington, IN). The Oasis™ Wound Dressing is provided in single thickness, 30 fenestrated sheets. It will be appreciated that SIS is readily available for use as a wound dressing.

While small intestine submucosa is available, other sources of submucosa are known to be effective for tissue remodeling. These sources include, but are not limited to, stomach, bladder, alimentary, respiratory, or genital submucosa. See, e.g., U.S. Patent Nos. 6,171,344, 6,099,567, and 5,554,389, hereby incorporated by reference. Further, it is known that these various submucosa materials may be derived from non-porcine sources, including bovine and ovine sources. Additionally, other collagen matrices are known, for example lamina propria and stratum compactum.

10 It is also known to use a vacuum treatment bandage for accelerating wound healing. A vacuum bandage is a bandage having a cover for sealing about the outer perimeter of the wound and under which a vacuum is established to act on the wound surface. This vacuum applied to the wound surface accelerates healing of chronic wounds. Typically, suction tubes are provided for drawing exudate away from the wound, and the suction tubes may be used to create the vacuum under the cover. If the cover is a flexible cover, which is typically more comfortable for the patient, a porous packing may be provided under the cover to provide the space in which the vacuum is formed. Additionally, it is known a heater within a wound treatment apparatus to promote healing. The following U.S. Patents establish the nature of vacuum and/or heat treatment bandages and devices: 6,095,992, 6,080,189,  
15 20, 6,071,304, 5,645,081, 5,636,643, 5,358,494, 5,298,015, 4,969,880, 4,655,754, 4,569,674, 4,382,441, and 4,112,947. All of such references are incorporated herein by reference for purposes of disclosing the nature of such vacuum or heat treatment of wounds.

As shown, for example, in U.S. Patent No. 5,645,081 (hereinafter the '081 patent), a method of treating tissue damage is provided by applying negative pressure to a wound. The negative pressure is provided in sufficient duration and magnitude to promote tissue migration in order to facilitate the closure of the wound. Fig. 1 of the '081 patent discloses an open cell polyester foam section covering the wound, a flexible hollow tube inserted into the foam section at one end and attached to a vacuum pump at another end, an adhesive sheet overlying the foam section, and tubing to adhere to the skin surrounding the wound in order to form a seal that allows the creation of a vacuum when the suction pump is operating. The '081 patent further

teaches use of negative pressure between about 0.1 and 0.99 atmospheres, and that the pressure can be substantially continuous, wherein the pressure is relieved only to change the dressing on the wound. Alternatively, the '081 patent teaches use of a cyclic application of pressure in alternating periods of application and non-  
5 application. In a preferred embodiment, pressure is applied in 5 minute periods of application and non-application.

The following pending applications, assigned to the same assignee as the present application is licensed, are also specifically incorporated herein by reference: U.S. Patent Application Serial No. 09/369,113 filed August 5, 1999 and  
10 titled Wound Treatment Apparatus, U.S. Patent Application Serial No. 09/725,352 filed November 29, 2000 and titled Vacuum Therapy and Cleansing Dressing for Wounds, and U.S. Patent Application Serial No. 09/725,666 filed November 29, 2000 and titled Wound Treatment Apparatus.

Various of prior art references teach the value of the vacuum bandage or the provision of vacuum to the surface of a chronic wound. Several Russian language articles exist that establish the efficacy of vacuum therapy. Examples of such prior art articles, each of which discusses the use of application of vacuum to a wound to promote healing, are as follows: Vacuum therapy in the treatment of acute suppurative diseases of soft tissues and suppurative wound, Davydov, et al. Vestn. Khir., Sept. 1988 ("the Sept. 1988 article"); Pathogenic mechanism of the effect of vacuum therapy on the course of the wound process, Davydov, et al. Khirurgiia, June 1990 ("the June 1990 article"); and Vacuum therapy in the treatment of suppurative lactation mastitis, Davydov, et al., Vestn. Khir., Nov. 1986 ("the Nov. 1986 article").

The Russian articles distinguish wound drainage from use of vacuum therapy for healing, and they report that vacuum therapy results in faster cleansing of the wound and more rapid detoxification than with the traditional incision-drainage method. The Nov. 1986 article describes the vacuum therapy protocol as 0.8 - 1.0 atmosphere for 20 minutes at the time of surgery, and subsequent 1.5 to 3 hour treatments at a vacuum of 0.1 to 0.15 atmosphere, twice daily. These Russian articles teach that use of negative pressure accelerates healing. The Russian articles further teach using this vacuum method to decrease the number of microbes in the wound. The June 1990 article teaches that vacuum therapy provides a significant antibacterial

effect. The June 1990 article describes the stepped up inflow of blood to the zone around the wound, which leads to an increase in the number of leukocytes reaching the focus of inflammation. Moreover, the Russian articles teach improvement of local blood circulation using vacuum therapy. The September 1988 article teaches 5 improved inflow of blood into the wound zone, which intensifies the repair processes. The June 1990 article teaches that vacuum therapy promotes mobilization of blood plasma, intertissue fluid, and lymph into the wound. The June 1990 article reports that cellular and non-cellular elements of connective tissue appear twice as quickly in wounds treated with vacuum therapy. Subsequent articles and patents further develop 10 the benefits obtained with vacuum therapy. The prior art, therefore, teaches the benefit and value of a vacuum bandage.

#### Summary of the Invention

According to the present invention, a wound care bandage is provided 15 that combines the advantages of SIS and vacuum therapy to control and enhance the flow of fluid from the wound bed and into the SIS material. The present invention, therefore, is a method for controllably drawing fluid from the surrounding tissue and into an SIS layer placed on the wound, thereby enhancing the healing and restructuring properties of the SIS.

20 The present invention comprises structure to provide a space above the SIS and the wound bed, in which space a vacuum is developed to cause blood flow from the wound bed into the SIS. Furthermore, the method contemplates controlling the vacuum level and the application time of the vacuum to present optimum blood flow from the wound bed into the SIS.

25 In preferred embodiments, the wound care bandage includes an SIS layer to be placed in contact with the wound bed. As mentioned above, the wound care bandage further includes a structure placed over the SIS layer to provide a vacuum space between the SIS layer and a cover placed over the structure and SIS layer. The cover is coupled to the patient's skin surrounding the wound to provide a 30 sealed environment. A vacuum source is coupled to the wound covering for communication with the vacuum space created by the structure. The vacuum source is used to create a vacuum within the sealed environment in order to draw blood from

the wound bed up through the SIS layer to promote the healing process. The vacuum suction is to be at a level sufficient to draw blood to the SIS layer, for example, 125 mm Hg. It will be appreciated, however, that varying levels of vacuum suction and varying protocols for the duration of application of vacuum are within the scope of the 5 present invention.

In further embodiments, the space-providing structure is a porous or reticulated pad or other structure having air passageways extending from the SIS layer to the cover. In still further embodiments, the space-providing structure may be a foam ring, or it may be the cover itself, provided that the cover is sufficiently rigid.

10 Thus, in one aspect of this invention a wound care bandage is provided comprising a collagen matrix formed for placement on a wound, a cover configured for placement over the wound to provide a sealed environment around the wound and adapted for communication with a vacuum source, and a structure for placement between the collagen matrix and the cover and configured to provide a vacuum space.

15 In preferred embodiments, the collagen matrix is a layer of submucosa.

20 In another aspect of this invention a wound care bandage is provided comprising an SIS layer adapted to be placed on a wound, and a cover configured to be placed over the wound and the SIS layer to provide a vacuum space between the SIS layer and an inside surface of the cover, the space being connectable with a vacuum source.

25 Still another aspect of this invention includes a method for promoting wound healing comprising the steps of providing a wound care bandage having an SIS layer adapted to be placed on a wound, a cover to be placed over the wound to provide a vacuum space above the wound, a structure to define the vacuum space between the SIS layer and the cover, and creating a vacuum within the vacuum space to controllably draw blood from the wound into the SIS layer placed over the wound.

30 Yet another aspect of this invention is directed to a method for promoting wound healing comprising the steps of applying an SIS layer to a wound surface, placing a support structure over the SIS layer, placing a cover over the wound, SIS layer and support structure to define a vacuum space, connecting the cover to a vacuum source, and creating a vacuum within the vacuum space.

An additional aspect of this invention is directed to a method for promoting wound healing comprising the steps of applying a collagen matrix to a wound surface, creating a vacuum space in communication with the wound and the collagen matrix, and generating a vacuum within the vacuum space in a magnitude and duration sufficient to draw blood from the wound into the collagen matrix.

5 A final aspect of this invention is a kit for promoting wound healing, the kit comprising a submucosa layer for contacting the wound, a porous pad, and a cover for creating a seal around the wound and configured for communication with a vacuum source.

10

#### Brief Description of the Drawings

The detailed description particularly refers to the accompanying figures in which:

15 Fig. 1 is a sectional view of a debrided wound and a wound care bandage showing an SIS layer, a porous pad or filler, and a cover of the wound care bandage, and further showing the cover of the wound care bandage in communication with a tube adapted to lead to a vacuum source;

Fig. 2 is a plan view of the SIS layer shown in Fig. 1 showing fenestrations in the SIS layer;

20 Fig. 3 is a sectional view of another debrided wound and another wound care bandage including an SIS layer, a walled structure to provide a vacuum space, a covering, and a vacuum tube positioned to lie under the cover and in communication with the vacuum space at one end and a vacuum source at another end;

25 Fig. 4 is a sectional view of another embodiment of the present invention showing another wound care bandage over a debrided wound and showing the bandage including an SIS layer, a ring-shaped structure defining a vacuum space in communication with the vacuum source, and a cover positioned over the structure; and

30 Fig. 5 is a sectional view of another embodiment of the present invention showing the bandage including a semi-rigid walled structure for defining a vacuum space in communication with the vacuum source.

Detailed Description of the Drawings

A wound care bandage 10 is provided, as shown in Figs. 1-5, for use with a debrided wound 12. Referring to Fig. 1, bandage 10 includes a small intestinal submucosa (SIS) layer 14 which lies adjacent to a wound surface 16 of wound 12.

5 Bandage 10 further includes a cover 18 for placement over wound 12 and a structure 20, 120, 220, or 320 positioned between SIS layer 14 and cover 18 in order to create a vacuum space 22. Cover 18 is coupled to a portion of the patient's skin 24 surrounding wound 12 in order to enclose wound 12, SIS layer 14, and structure 20, 120, 220, or 320 within a sealed environment. Bandage 10 further includes a means

10 for communicating vacuum space 22 with a vacuum source 26. The wound care bandage 10, therefore, combines the healing properties of the SIS layer 14 with the acceleration provided by the vacuum therapy.

SIS layer 14, which is applied directly to wound surface 16, may be fenestrated (or perforated) to prevent fluid accumulation below the SIS layer 14. Such 15 fenestrations 28 are shown, for example, in Fig. 2. Equipment is available for fenestrating skin grafts and it is contemplated that such equipment could also be used to fenestrate SIS layer 14. These fenestrations 28, or perforations, in the SIS layer 14 permit blood from the wound 12 to migrate upwardly into the SIS layer 14 and deposit cells to start the tissue growth in the SIS framework of the SIS layer 14.

20 Further, SIS layer 14 may be formed to include one single sheet of SIS or multiple sheets of SIS. For SIS layer 14 including multiple SIS sheets, the sheets may be positioned in any number of orientations relative to each other. It is further within the scope of the disclosure for SIS layer 14 to have any reasonable thickness for its use in bandage 10. It is also known in the art that larger sheets of submucosa 25 may be formed by fusing multiple strips of submucosa tissue. See U.S. Patent No. 5,711,969, already incorporated by reference. In a preferred embodiment, SIS layer 14 is sized to fit the wound and is flexible in order to allow the SIS layer 14 to conform to any complex wound or wound surface. Additionally, it is known to treat wounds with SIS provided in fresh, frozen, or lyophilized forms. Lyophilized SIS 30 may be used in the dried form, or it may be hydrated prior to use.

In some optional embodiments, a biological glue 30 is provided between the debrided wound surface 16 and the SIS layer 14 in order to hold the SIS

layer 14 in a stationary position against the wound surface 16, as shown, for example, in Fig. 1. One type of biological glue 30 used may be a fibrin sealant, for example. It is within the scope of this disclosure, however, to include any type of biological glue sufficient for holding the SIS layer 14 stationary relative to wound surface 16.

5 SIS is intended to identify porcine small intestine submucosa. While reference is made herein to SIS, it will be appreciated that small intestine submucosa may be obtained from other animal sources, including cattle, sheep, and other warm-blooded mammals. Further, other sources of submucosa from various tissue are known to be effective for tissue remodeling as well. These sources include, but are  
10 not limited to, stomach, bladder, alimentary, respiratory, and genital submucosa. Such submucosa-derived matrices comprise highly conserved collagens, glycoproteins, proteoglycans, and glycosaminoglycans. Additionally, other collagen matrices are known that can act as a biological scaffolds. Thus, it is understood that while the preferred embodiment uses SIS, other collagen matrices may be used within the scope  
15 of this invention.

The structure of bandage 10, is provided to form vacuum space 22 between SIS layer 14 and cover 18. A structure supports cover 18 while providing air passageways to the wound surface 16 and the SIS layer 14. As shown in Fig. 1, the structure is preferably a reticulated or porous filler or pad 20 having airflow  
20 passageways (not shown) extending throughout pad 20. It is preferred that pad 20 be rather flexible to conform to any complex wound or wound surface and to be comfortable for the patient. Further, it is preferred that the thickness of the structure is selected to provide proper vacuum access to all parts of the wound to be served. It is further preferred that a thickness,  $t$ , of the reticulated flexible pad 20 be  
25 approximately one to two centimeters. The reticulated or porous pad 20 may be cut by the surgeon to be larger than the SIS layer 14 and even larger than the wound 12.

Although porous pad 20 has been described above, it is within the scope of this disclosure to include any such structure which functions to create a space between the SIS layer 14 and the cover 18 and permits air flow from the wound 12 to  
30 transmit negative pressure to the wound surface 16. As shown in Fig 3, the structure 120 may be gauze, or, as shown in Fig. 4, the structure may be a foam ring 220 or other such ring to position cover 18 in spaced-apart relation to SIS layer 14. Ring 220

includes an aperture defined by an inner wall 221 of the ring 220. The vacuum space 22 is thus defined by the SIS layer 14, the cover 18, and the inner wall 221 of ring 220.

Further, as shown in Fig. 5, for example, the structure may be a rigid 5 dome or a preferably semi-rigid dome 320 which supports the cover 18 above the SIS layer 14. Semi-rigid dome 320 includes a lower member 322 adapted to lie adjacent the patient's skin surrounding wound 12, an upper member 324 normally spaced-apart from SIS layer 14, and a middle member 326 for supporting the upper member 324 in spaced-apart relationship with the SIS layer 14. Semi-rigid dome 320 may be 10 generally dome-shaped, for example, as well. Although such examples as porous pad 20, foam ring 220, and semi-rigid dome 320 have been provided as examples for the structure, it is within the scope of this disclosure for bandage 10 to include any space providing structure above the SIS layer 14 and below the cover 18 for communication with a vacuum service 26.

15 Cover 18 of the bandage 10 lies over the space-providing structure to fully enclose the structure, SIS layer 14, and wound 12. Cover 18 is coupled to the patient's skin 24 which surrounds the wound 12. For example, cover 18 may be a thin transparent, non-porous adhesive sheet to adhere to the surface of the skin 24 about the wound 12 to provide a vacuum enclosure. An adhesive 33 for coupling cover 18 20 to skin 24 is shown in Figs. 1 and 3-5. A product such as Tegaderm™ (3M Health Care Ltd., (St. Paul, MN)) would be suitable for the cover, for example. It is within the scope of this disclosure, however, to include any suitable non-porous impermeable or semi-permeable sheet. While a flexible or semi-rigid sheet is preferred for patient comfort, a rigid cover, such as a glass dome, is within the scope of this invention. 25 When a rigid cover is used, a separate space-providing structure is not needed, as the rigid cover may be configured to provide the vacuum space.

In order to encourage blood flow to the wound 12 and wound surface 16, vacuum space 22 of wound care bandage 10 is connected with vacuum source 26. A vacuum tube 32 may be provided, for example, for fluid communication with 30 vacuum space 22 and vacuum source 26. As shown in Fig. 1, vacuum tube 32 is coupled to cover 18 and in communication with vacuum space 22. A first end 40 of

tube 32 includes a collar 34 coupled to an aperture of the cover 18. As shown diagrammatically, a second end 42 of tube 32 is coupled to vacuum source 26.

In other embodiments, as shown in Figs. 3-5, for example, tube 32 is placed under cover 18 and into vacuum space 22. Cover 18 is sealed around tube 32 5 in order to create a sealed environment for the vacuum to function properly. The vacuum may be provided by a suction tube disposed in the space and configured to draw excess wound drainage away from the wound. Another type of fluid connection system between a wound dressing and a vacuum source is disclosed in U.S. Patent No. 4,969,880, incorporated herein by reference. Furthermore, while first end 40 of 10 tube 32 is shown in Figs. 3 and 4 as being located in the structure 120 or 220, it is understood that first end 32 may be placed directly on the SIS layer 14. Additionally, it is understood that tube 32 may be a Jackson-Pratt type drain, with holes distributed along its length adjacent first end 32.

The vacuum may be provided in vacuum space 22 for controlled 15 periods of time. For example, initially, the vacuum may be applied for a sufficient time to draw blood into the SIS layer 14, such as up to 125 mm Hg, for example. It will be appreciated that this invention contemplates developing different protocols for amounts of vacuum and application times. It will also be appreciated that the vacuum may be provided by a perforated tube positioned and configured to carry away excess 20 wound drainage.

In treating wound 12, a caretaker first cleans and prepares the wound surface 16. Once wound surface 16 is prepared, bandage 10 is to be applied to the wound. SIS layer 14 is positioned over the wound 12 to cover the prepared wound surface 16. Structure 20, 120, 220, or 320 is placed over the SIS layer 14 to define the 25 vacuum space and cover 18 is placed over the wound 12, SIS layer 14, and structure 20. Cover 18 is connected to a vacuum source 26. Finally, suction is applied to the vacuum space 22 in sufficient magnitude and duration to draw blood from the wound into the SIS layer 14. Optionally, a biological glue 30 may be placed on the wound surface 16 prior to application of the bandage 10.

30 Vacuum may be applied at any magnitude or duration to promote inflow of blood from the wound into the layer of SIS. Preferably, vacuum may be applied from 0.1 to 0.99 atmospheres, and more preferably 0.1 to 0.15 atmospheres.

In one embodiment, vacuum is applied essentially continuously until healing takes place. In another embodiment, vacuum is used in periods of application and non-application, and the structure and cover may be removed during periods of non-application. These alternating periods may include one or two periods of application 5 each day for several days. In another embodiment, the negative pressure is applied in 5 minute periods of application and non-application.

It is known that SIS can be integrated into the wound and restructured to resemble the surrounding tissue. Thus, while the magnitude and duration of application of vacuum may vary, in a preferred embodiment the SIS remains on the 10 surface of the wound for the duration of treatment. In optional embodiments, additional layers of SIS may be added as the SIS is integrated into the wound. The additional layers may be smaller pieces to be placed on localized areas of integration, or, because the vacuum promotes blood flow into the SIS layer, may be full size pieces conforming to the size of the wound surface.

15 *500*  
*BS* Thus, in one embodiment the present invention is a method for treating wounds comprising the steps of preparing the wound surface, applying a bandage to the wound, the bandage having an SIS layer secured over the wound and a cover above the wound and the SIS layer to define a vacuum space between the wound and SIS layer, and applying suction to the vacuum space to draw blood from the wound 20 into the SIS layer.

Although this invention has been described in detail with reference to certain embodiments, variations and modifications exist within the scope and spirit of the invention as described and defined in the following claims.